

04/24/00
JCS06 U.S. PTO

APPLICATION
FOR
UNITED STATES LETTERS PATENT

TITLE: MEDICAL DEVICE BALLOONS CONTAINING
THERMOPLASTIC ELASTOMERS

APPLICANT: BRUCE HAMILTON AND RONALD SAHATJIAN

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EL 228 032 763 US

I hereby certify under 37 CFR §1.10 that this correspondence is being deposited with the United States Postal Service as Express Mail Post Office to Addressee with sufficient postage on the date indicated below and is addressed to the Commissioner of Patents, Washington, D.C. 20231.

Date of Deposit April 24, 2000

Signature

Typed or Printed Name of Person Signing Certificate

09557259-042400

MEDICAL DEVICE BALLOONS CONTAINING
THERMOPLASTIC ELASTOMERS

BACKGROUND OF THE INVENTION

5 The present invention relates to catheters that can be placed in bodily conduits. The invention particularly relates to dilatation balloons and catheters using such balloons for administering treatments to widen constricted passages in, for example, angioplasty, valvuloplasty, or
10 urological procedures.

 One example of such a procedure, angioplasty, is used to treat a stenosis, i.e. to restore adequate blood flow to a region of a blood vessel which has been narrowed to such a degree that blood flow is restricted. Frequently the
15 stenosis can be expanded so that the vessel will permit an acceptable blood flow rate. Coronary angioplasty, for example, includes the insertion of a balloon catheter through a patient's coronary artery to an arterial stenosis and injecting a suitable fluid into the balloon to inflate it, hence expanding the stenosis radially outwardly.
20 Angioplasty has proven to be a successful alternative to coronary arterial bypass surgery.

 Typically, balloon catheters have a balloon fastened at at least one end around the exterior of a hollow catheter
25 shaft. The hollow interior of the balloon is in fluid flow relation with the hollow interior of the shaft. The shaft then may be used to provide a fluid supply for inflating the balloon.

 Presently used catheter balloons may be classified as
30 compliant or non-compliant balloons. Compliant balloons expand and stretch with increasing pressure within the balloon, and are made from such materials as polyethylene or polyolefin copolymers. Non-compliant balloons, made from such materials as polyethylene terephthalate (PET) or

polyamides, remain at a preselected diameter as the internal balloon pressure increases beyond that required to fully inflate the balloon.

Compliant balloon materials provide a degree of softness to the balloon which aids its passage through, e.g., blood vessels with minimal trauma. Known compliant balloon materials also can display good abrasion and puncture resistance at thicknesses typically used for medical device balloons. However, as mentioned above, they do not remain at the desired diameter with increasing pressure. Such compliant balloons also lack sufficient hoop strength to achieve high dilating forces.

A non-compliant balloon, that is one remaining at a preselected diameter regardless of increasing pressure, is often desirable. Typical non-compliant balloon materials do not exhibit the same degrees of softness and abrasion resistance as the compliant balloons.

It would be desirable, for many treatment conditions, to have a dilatation balloon exhibiting the combined characteristics of softness, abrasion and puncture resistance, hoop strength, and the ability to maintain a preselected diameter as the internal pressure within the balloon is increased. The balloon described herein was developed to address that need.

SUMMARY OF THE INVENTION

In one embodiment, the invention is a dilatation balloon for use in a medical catheter device. The dilatation balloon includes a thermoplastic elastomer in combination with a non-compliant structural polymeric material. The preferred thermoplastic elastomer includes an engineering thermoplastic elastomer, for example a polyether glycol/polybutylene terephthalate block copolymer. The thermoplastic elastomer may be combined with the non-

compliant structural polymeric material as an outer elastomeric layer disposed upon an inner structural layer of the non-compliant structural polymeric material, as both an inner elastomeric layer and an outer elastomeric layer
5 disposed upon an intermediate structural layer of the non-compliant structural polymeric material, or as a blend of the thermoplastic elastomer and the non-compliant structural polymeric material.

In another embodiment, the invention is a catheter for
10 insertion into a bodily conduit. The catheter includes a shaft having a lumen internal to the shaft for delivery of fluid inflation media, and a dilatation balloon bonded to the shaft and defining a chamber. The chamber is in fluid communication with the lumen to permit inflation of the
15 chamber. The dilatation balloon includes a thermoplastic elastomer in combination with a non-compliant structural polymeric material, as described above with respect to the balloon in accordance with the invention.

In yet another embodiment, the invention is a method
20 for fabricating a dilatation balloon for use in a medical catheter device. The method involves producing a generally cylindrical balloon blank from a combination of a thermoplastic elastomer and a non-compliant structural material, and shaping the balloon blank to produce the
25 dilatation balloon.

The balloon blank may be produced by disposing an elastomeric layer including the thermoplastic elastomer upon a structural layer including the non-compliant structural polymeric material to produce a layered, generally
30 cylindrical balloon blank. The thermoplastic elastomer and the non-compliant structural polymeric material may be coextruded to produce the balloon blank. Alternatively, the balloon blank may be produced by preparing a blend of the thermoplastic elastomer and the non-compliant structural

polymeric material. A generally cylindrical balloon blank is formed from the blend, and the balloon blank is then shaped to produce the dilatation balloon. The balloon blank may be shaped to have a generally cylindrical central portion and generally conical end portions.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, together with other objects, advantages, and capabilities thereof, reference is made to the following Description and appended Claims, together with the Drawings in which:

Figure 1 is an elevation view of a medical balloon catheter, partly in section, in accordance with one embodiment of the present invention;

Figure 2a is a cross-sectional view of the balloon of Figure 1, taken along line 2a-2a, showing the balloon layers;

Figures 2b, 2c, and 2d are cross-sectional views similar to that shown in Figure 2a (omitting the shaft distal end) illustrating balloons in accordance with alternate embodiments of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An exemplary embodiment of the balloon and catheter in accordance with the invention is described herein. The angioplasty catheter includes a balloon mounted at the distal end of a shaft including at least one lumen for inflation of the balloon. The balloon is a generally tubular body fabricated from a combination of a non-compliant structural polymeric material and a thermoplastic elastomer (TPE). The combination may be in the form of coextensive coextruded layers, otherwise disposed layers, blends, or blended layers of these materials. Once the catheter is in position within the patient's artery, a fluid

inflation medium may be introduced via the lumen to inflate the balloon to the preselected desired diameter.

5 The term "structural polymer" or "structural polymeric material", as used herein, is intended to mean any polymeric material suitable for use in medical balloons and compatible with the TPE selected. As mentioned above, the term "non-compliant", as used herein, is intended to mean remaining at a preselected diameter as the internal pressure in the balloon is increased above that required to fully inflate the balloon. The structural layer of the balloon must be self supporting and capable of supporting at least one TPE layer thereon. Suitable non-compliant structural polymeric materials include, for example, modified polyesters, polyethylene terephthalate (PET), modified polybutylenes, 10 polyvinyl chlorides, polyamides (e.g. Nylon), etc., or a combination thereof. Preferred are biaxially oriented non-compliant structural materials; most preferred is biaxially oriented PET.

20 The term "thermoplastic elastomer" or "TPE", as used herein, is intended to mean a polymeric material that combines the mechanical properties of a thermoset rubber, i.e. resiliency, softness, and toughness, with the production economics of a thermoplastic polymer. The TPEs include styrenic block copolymers, polyolefin blends (TPOs), elastomeric alloys, thermoplastic polyurethanes (TPUs), 25 thermoplastic copolyesters, and thermoplastic polyamides. These materials have varying patterns of hard and soft segments included in the polymer chain or compound. The hard segments melt or soften at processing temperatures, producing a melt processable material for ease of 30 fabrication. In block copolymer TPEs, the hard and soft regions are in the same polymer chain. Descriptions of various types of TPEs may be found in Modern Plastics Encyclopedia 1988, Vol. 64, No. 10A, pp. 93 - 100 (October

1987), and in Modern Plastics Encyclopedia 1990, Vol. 66, No. 11, pp. 122 - 131 (Mid-October 1989), both incorporated herein by reference.

5 The preferred TPEs for the balloon described herein are engineering thermoplastic elastomers (ETEs), which are randomized block copolymers having polyester crystalline hard segments and amorphous glycol soft segments. ETEs possess flexibility over a useful range of strain, and are quite extensible when operating within their elastic limit. 10 Another advantage of ETEs for medical devices is their resistance to most radiation, permitting sterilization by such means, although they must be protected from UV radiation.

15 The more preferred ETEs for use in the medical devices described herein are randomized block copolymers of polyether glycol and polybutylene terephthalate (PBT). These combine crystalline PBT hard segments with melt stable glycol soft segments, and come in a wide range of stiffness grades. Most preferred are those having a flexural modulus 20 of about 21,000 - 440,000 psi (as measured in accordance with ASTM D790, Method 1), for example Hytrel® polymers (available from E.I. DuPont de Nemours and Company, Wilmington, DE).

25 As mentioned above, the combination of a TPE and a non-compliant structural polymer may be in the form of blends, coextensive coextruded layers, otherwise disposed layers, or layers of blends of these materials. Suitable blends include homogeneous and near-homogeneous blends, which may be prepared by such conventional means as stirring, mixing, 30 compounding, etc.

In a layered embodiment of the balloon, one or more base structural polymer layers are formed, for example by extrusion, from a non-compliant structural polymer, as described above. Alternatively, the base non-compliant

structural layer is formed from a blend of two or more structural polymers, a blend of a structural polymer with a minor amount of another polymeric material, or a blend of a structural polymer with a minor amount of a TPE. As used
5 herein, the term "minor amount" is intended to mean an amount selected to make the additive no more than a secondary component, for example less than 50 weight %, of the blend. The material of the structural layer, however, must still contribute to the balloon the properties
10 described above for the structural material. This base structural layer (or layers) is typically at least about 0.2 - 1.5 mil thick, and gives the balloon its tensile strength so that the balloon wall is self supporting.

At least one additional, elastomeric outer layer about
15 0.2 - 0.5 mil thick is coextruded with or otherwise disposed on the base layer and, typically, generally coextensive therewith. Normally, the elastomeric layer is significantly thinner than the structural layer. The material of this outer layer is based on a thermoplastic elastomer (TPE)
20 which, in some embodiments, may be combined in a blend with other polymers known to be suitable for medical balloons. The amount of these other polymers, however, should be within limits which would permit such a blend to contribute to the balloon the properties described herein for such an
25 elastomeric layer. Especially preferred for this outer elastomeric layer is a blend of an ETE with a small amount of a non-compliant structural polymer, e.g. a blend of about 1 - 10 weight % PET, remainder Hytrel elastomer.

In some of the above-described layered balloons, it may
30 be advantageous to dispose or coextrude an adhesive or other polymer layer between two or more of the layers. In one embodiment, an adhesive layer may be included to improve adhesion between coextensive balloon layers and, if desired, may be applied for adhesion of the medical device balloon to

00440-0522560

a catheter shaft. In another embodiment, an additional polymer layer may be included to contribute other desirable properties to the balloon, for example to contribute further to the softness and/or foldability of the balloon. In other
5 embodiments, the adhesive or other polymer may be blended with a structural and/or elastomeric layer to contribute its properties to the balloon. For example, in a three layer balloon an adhesive polymer may be blended with a structural polymer layer to improve adhesion of inner and outer ETE
10 layers to the structural layer. The amount of adhesive or other polymer in such a blend is selected to provide the desired enhancement of properties while permitting the blend to possess the properties described herein for such a layer. Examples of adhesive materials for forming this layer or
15 blend are Bynel® adhesive resin (E.I. DuPont de Nemours and Company, Wilmington, DE) or Plexar® adhesive resin (Quantum Chemical Corp., Cincinnati, OH). Selar® modified PET resin (E.I. DuPont de Nemours and Company, Wilmington, DE) is a suitable polymer intermediate layer or blend additive for
20 improving softness and foldability of the balloon. Bynel and Plexar resins can also serve to improve the abrasion resistance and puncture resistance of the balloon, and provide it with a softer feel.

In another embodiment of the balloon, a single layer
25 balloon wall is fabricated from a blend of a non-compliant structural polymer and a TPE. The TPE, preferably the above-described polyether glycol/PBT block copolymer, is blended with the structural polymer in a TPE-to-structural polymer ratio selected to provide the desired degree of
30 softness and abrasion resistance to the balloon without unduly compromising the hoop strength or the desired inflated diameter. As mentioned above, such blends may be homogeneous or near-homogeneous, and may be blended in any of several ways known in the art. Typical polymer ratios

for such a single layer balloon are about 40:60 to 60:40, TPE:structural polymer.

5 In other embodiments, the TPE/structural polymer blend used in the above-described single layer balloon may be used as a structural layer in combination with other layers, or may be blended to be used as an elastomeric layer in a layered balloon. The polymer ratio for a blended structural layer of such a balloon is typically about 40:60 to 60:40, TPE:structural polymer; that for elastomeric inner or outer
10 layers is typically about 30:70 to 60:40, TPE:structural polymer. The exact ratios within these ranges to produce specific balloon characteristics are empirically determined with minimal experimentation. These blended layers may be used with or without an adhesive or softening component or layer as described above
15

The use of thermoplastic elastomers in medical device balloons results in a superior balance of balloon properties when used as one or more outer layers over a structural layer of currently used balloon materials or other suitable structural polymers, or as outer and inner layers
20 surrounding such a structural layer. Alternatively, this superior balance of balloon properties may be achieved by using TPEs as a blend with currently used balloon materials or other suitable structural polymers. By varying the fabrication method and/or layer materials and/or blend materials and ratios, as described herein, the structural and surface properties of the ETE containing balloon may be precisely tailored for a desired procedure.
25

The description below of various illustrative
30 embodiments shown in the Drawings refers to engineering thermoplastic elastomers (ETEs). However, it is not intended to limit the scope of the present invention, but merely to be illustrative and representative thereof.

Referring now to Figure 1, catheter 10 in accordance with one embodiment of the present invention includes shaft 12 having lumens 14 and 16 extending therethrough, and having a proximal end 18 and a distal end 20. Distal end 20 extends to catheter tip 22. Dilatation balloon 24, shown in Figure 1 in its inflated state, surrounds shaft distal end 20. Balloon proximal end 26 is bonded to shaft distal end 20 at a point spaced from tip 22, and balloon distal end 28 is bonded to shaft distal end 20 near tip 22, each, e.g., by a suitable adhesive (not shown). Balloon 24 defines balloon chamber 30 which is in fluid communication with lumen 14 via aperture 32. Thus, balloon 24 may be inflated by passing a fluid inflation medium through lumen 14 and aperture 32 into chamber 30. Lumen 16 may be used, for example, to contain a guidewire or other device.

As shown in Figures 1 and 2a, dilatation balloon 24 surrounding shaft distal end 20 is made up of two layers, 34 and 36, of differing polymeric materials. Inner layer 34 is a structural layer of, e.g., PET approximately 0.2-1.0 mil thick. Outer layer 36 has been co-extruded to be co-extensive with layer 34, and is a layer of ETE, e.g. Hytrel copolymer, about 0.2 - 0.5 mil thick.

Figures 2b, 2c, and 2d each illustrate alternate embodiments of the balloon of the invention in cross-section, similarly to Figure 2a. For simplicity, however, shaft distal end 20, although actually present in the same position as shown in Figure 2a, is not depicted in the view shown in Figures 2b-2d.

Figure 2b illustrates in cross-section dilatation balloon 24a, fabricated from single layer 38 of a blend of a structural polymer, e.g. polyethylene terephthalate, with an ETE, for example Hytrel copolymer.

Figure 2c shows balloon 24b fabricated from, e.g., coextruded triple layers, 34a, 36a, and 40. Structural

layer 34a and ETE outer layer 36a are similar to layers 34 and 36 of Figures 1 and 2a. In the embodiment illustrated in Figure 2c, however, an additional ETE layer, innermost layer 40, has been coextruded to be coextensive with layers 34a and 36a and internal thereto. Innermost layer 40 provides additional tear resistance to protect the balloon wall from damage from internal pressure. Layer 40 also provides for a softer, more foldable balloon.

Figure 2d illustrates balloon 24c, fabricated in a similar manner to balloon 24 of Figures 1 and 2a, and having inner structural layer 34b and ETE outer layer 36b. Thin intermediate adhesive layer 42 of, e.g., Bynel resin is coextruded with and between layers 34b and 36b to be coextensive therewith, acting to bond together more securely layers 34b and 36b.

In other alternate embodiments, one or more of layers 34, 34a, and 34b may be a blend of a structural polymer with an ETE. Also alternatively, one or more of layers 36, 36a, 36b, or 40 may be a blend of ETE with a structural polymeric material. In the embodiment of Figure 2c, a sufficient amount of a polymeric adhesive to improve bonding of the layers may be blended into layer 34a. Alternatively, layer 34a may be, e.g., a Selar resin balloon softening layer. Also alternatively, the adhesive or other polymeric additive may be blended into, e.g., layer 34, 36, 36a, 40, etc., as described above. In other alternate embodiments, not shown, the balloon may have more than one innermost and/or outermost ETE layer. For example, a balloon may be similar to that shown in Figure 2a but have an additional ETE layer between layers 34 and 36, or may be similar to that shown in Figure 2c but have an additional ETE layer between layers 34a and one or both of layers 36a and 40.

In operation, the catheter device including the novel dilatation balloon is inserted into the vasculature of a

patient, and is manipulated into position by torquing, pushing, and pulling. Positioning of the catheter is aided by the softness of the balloon provided by the TPE component of the balloon. Once the catheter is in position, the
5 balloon is inflated to the preselected diameter, then deflated via the central lumen of the shaft. The inclusion of a non-compliant structural polymer in the balloon makes possible such preselection of the diameter. Upon completion of the dilation procedure and deflation of the balloon, the
10 catheter is removed from the patient. Removal of the catheter is also aided by the softness contributed to the balloon by the TPE component.

The invention described herein presents to the art novel, improved catheters and composite medical device
15 balloons including thermoplastic elastomers as (a) one or more layers in addition to one or more layers of currently used balloon structural materials or other suitable structural polymers, or (b) as a blend with such materials. The inclusion of TPE results in a superior balance of
20 balloon properties. For example, softer feel; superior abrasion and puncture resistance; lower required insertion, placement, and withdrawal forces; lower balloon resistance to inflation and deflation pressure; superior refoldability, with fold memory; and the ability to maintain a preselected
25 diameter are all achievable in a single balloon fabricated as described herein. Thus, the balloon described herein can provide a non-compliant balloon with the softness of a compliant balloon, as well as a soft balloon with ranges of burst strength and hoop strength equivalent to those of
30 harder balloons. The use of the adhesives and other layers or layer additives described herein, especially the Bynel and Plexar adhesives and Sellar additive described, can offer advantageous adhesive and/or softening properties. By varying the fabrication method and/or layer or blend

materials and ratios as described herein, the balance of structural and surface properties of the TPE containing balloon may be precisely tailored for a specific procedure.

5 While there has been shown and described what are at present considered the preferred embodiments of the invention, it will be apparent to those skilled in the art that modifications and changes can be made therein without departing from the scope of the present invention as defined by the appended Claims.

00440 35225500